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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,016	03/23/2004	David Feygin	115-004US	4798
22897 7590 01/08/2008 DEMONT & BREYER, LLC			EXAMINER	
. 100 COMMON	IS WAY, Ste. 250		FRISBY, KESHA	
HOLMDEL, NJ 07733			ART UNIT	PAPER NUMBER
			3714	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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	Application No.	Applicant(s)
	10/807,016	FEYGIN ET AL.
Office Action Summary	Examiner	Art Unit
	Kesha Frisby	3714
The MAILING DATE of this communication a Period for Reply	ppears on the cover sheet w	ith the correspondence address
A SHORTENED STATUTORY PERIOD FOR REP WHICHEVER IS LONGER, FROM THE MAILING - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory perions are reply within the set or extended period for reply will, by state the provision of the pro	DATE OF THIS COMMUNI 1.136(a). In no event, however, may a not will apply and will expire SIX (6) MOI ute, cause the application to become A	CATION. reply be timely filed NTHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133).
Status		
Responsive to communication(s) filed on 29 This action is FINAL. 2b) ☐ The 3) ☐ Since this application is in condition for allow closed in accordance with the practice under	nis action is non-final. vance except for formal mat	•
Disposition of Claims		
4) ⊠ Claim(s) 1-40 is/are pending in the application 4a) Of the above claim(s) is/are withdrest is/are allowed. 5) □ Claim(s) is/are allowed. 6) ⊠ Claim(s) 1-40 is/are rejected. 7) □ Claim(s) is/are objected to. 8) □ Claim(s) are subject to restriction and	rawn from consideration.	
Application Papers		
9) The specification is objected to by the Exami 10) The drawing(s) filed on is/are: a) and an applicant may not request that any objection to the Replacement drawing sheet(s) including the correction. 11) The oath or declaration is objected to by the	ccepted or b) objected to ne drawing(s) be held in abeya ection is required if the drawing	nce. See 37 CFR 1.85(a). g(s) is objected to. See 37 CFR 1.121(d).
Priority under 35 U.S.C. § 119		• .
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority docume 2. Certified copies of the priority docume 3. Copies of the certified copies of the priority docume application from the International Bure * See the attached detailed Office action for a li	ents have been received. ents have been received in Ariority documents have been eau (PCT Rule 17.2(a)).	Application No received in this National Stage
Attachment(s)	, , , , , , , , , , , , , , , , , , , 	O
 Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 12/4/2007. 	Paper No	Summary (PTO-413) (s)/Mail Date Informal Patent Application

DETAILED ACTION

Status of Claims

After the amendment filed on 10/29/2007, claims 1-40 are pending.

Information Disclosure Statement

1. The information disclosure statement filed 12/4/2007 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the Foreign Patent Document does not include a translation. The examiner is unable to determine what the document entails since it is in a foreign language. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2, 25, 27, 28, 35 & 38-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Rosenberg (U.S. Patent Number 6,654,000).

Referring to claim 1, Rosenberg discloses pseudo skin (barrier 22); a receiver (trocar 24), wherein said receiver receives an end effector (laparoscopic tool 18); and a first device (mechanical apparatus 25) for performing a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure, wherein said receiver and said first device are disposed beneath said pseudo skin and are covered by said pseudo skin (Fig. 1 & column 5 lines 37-56).

Referring to claim 2, Rosenberg discloses wherein an insertion region for said end effector is defined at a site at which said end effector is received by said receiver, and wherein said insertion region is proximal to a first region of said pseudo skin (Fig. 1 and the associated text).

Referring to claim 25, Rosenberg discloses a housing (within the "body" of the patient); an end effector (laparoscopic tool 18), wherein said end effector is inserted into said housing during the performance of a simulated vascular-access procedure (Fig. 1 & the associated text); and a plurality of mechanisms (mechanical apparatus 25 and trocar 24), wherein said plurality of mechanisms are contained completely within said housing (Fig. 1 & column 5 lines 37-56), and wherein said plurality of mechanisms include: (a) a first mechanism (mechanical apparatus 25) is for simulating a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure; and (b) a second mechanism (trocar 24) for receiving said end effector.

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Referring to claim 27, Rosenberg discloses wherein said plurality of mechanisms are disposed beneath a pseudo skin (Fig. 1 & column 5 lines 37-56).

Referring to claim 28, Rosenberg discloses wherein said mechanisms includes a third mechanism (column 11 line 47 – column 12 line 2) for simulating a second skin-interaction technique, and wherein said end effector is at least one of either a needle or a catheter (column 6 lines 4-13)

Referring to claim 35, Rosenberg discloses a pseudo skin (barrier 22); a plurality of mechanisms with which a user interacts for simulating a vascular- access procedure (mechanical apparatus 25 and trocar 24), wherein said plurality of mechanisms are disposed under said skin; and a housing (within the "body" of the patient), wherein said housing contains said plurality of mechanisms (Fig. 1 & column 5 lines 37-56).

Referring to claim 38, Rosenberg discloses wherein at least one of either a needle or catheter is disposed outside of said housing until inserted therein during a simulated vascular-access procedure (Fig. 1 & the associated text).

Referring to claim 39, Rosenberg discloses further comprising a data processing system, wherein said data processing system receives signals from sensors that are associated with said plurality of mechanisms (column 10 lines 22-24).

Referring to claim 40, Rosenberg discloses wherein said plurality of mechanisms comprise discrete devices, wherein a first of said devices (column 11 line 47- column 12 line 2) is for enabling a user to perform a skin-stretch technique, a second of said devices (trocar 24) is for receiving a needle or catheter or both, and a third of said

devices (column 12 lines 46-49) is for enabling a user to perform at least one of either a palpation technique or an occlusion technique.

Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claims 3-24 & 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg in view of Pugh (U.S. Publication Number 2003/0031993).

 Referring to claim 3, Rosenberg discloses wherein: said first skin-interaction technique comprises at least one of either palpation or occlusion (column 12 lines 46-49).

 Rosenberg does not disclose a second region of said pseudo skin is accessible to perform said first skin-interaction technique; and said first region of said pseudo skin is closer to a user than said second region of said pseudo skin when said user is using said apparatus. However, Pugh teaches a second region of said pseudo skin is accessible to perform said first skin-interaction technique; and said first region of said pseudo skin when said user is using said apparatus (paragraphs 0041 & 0042 & Fig. 3). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a second region, as disclosed by Pugh, incorporated into Rosenberg in order to determine the quality of an examiner's palpation techniques.

Referring to claims 4 & 13, Rosenberg discloses the apparatus of claims 2 & 10. Rosenberg does not disclose further comprising a second device for performing a second skin-interaction technique, wherein said second device is disposed beneath said pseudo skin and is covered by said pseudo skin. However, Pugh teaches further comprising a second device (paragraph 0012) for performing a second skin-interaction technique, wherein said second device is disposed beneath said pseudo skin and is covered by said pseudo skin (paragraphs 0012 & 0013). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a second device, as disclosed by Pugh, incorporated in to Rosenberg in order to teach palpation or manual assessment of body or anatomical surfaces.

Referring to claim 5, Rosenberg discloses the apparatus of claim 4. Rosenberg does not disclose wherein: said second skin-interaction technique comprises skin stretching, a region of said pseudo skin is accessible to perform said second skin-interaction technique; and said region of said pseudo skin is closer to a user than said first region of said pseudo skin when said user is using said apparatus. However, Pugh teaches wherein: said second skin-interaction technique comprises skin stretching (Figs. 14C, 15 & 16), a third region of said pseudo skin is accessible to perform said second skin-interaction technique (Figs. 15-17); and said third region of said pseudo skin is closer to a user than said first region of said pseudo skin when said user is using said apparatus (One region would be closer to a user then another region, depending on the location of the user with respect to the apparatus). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include skin-stretching and a third

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region, as disclosed Pugh, incorporated into Rosenberg in order to perform assessments and determine the different forces, pressures or textures in different regions.

Referring to claim 6, Rosenberg discloses the apparatus of claim 1. Rosenberg does not disclose further comprising a housing, wherein said housing has an anterior portion, a posterior portion, an upper surface and a lower surface wherein, in use: said anterior portion is proximal to a user; said posterior portion is distal to said user; said lower surface is proximal to a support surface on which said apparatus resides; and said upper surface is distal to said support surface. However, Pugh teaches further comprising a housing, wherein said housing (Figs. 1, 8 & 15) has an anterior, a posterior portion, an upper surface and a lower surface (i.e., upper and lower surfaces) (Fig. 3 & paragraphs 0041 & 0042) wherein, in use: said anterior portion is proximal to a user (One portion would be closer to a user then another portion, depending on the location of the user with respect to the apparatus); said posterior portion is distal to said user (One portion would be closer to a user then another region, depending on the location of the user with respect to the apparatus); said lower surface is proximal to a support surface (104) on which said apparatus resides (paragraph 0056); and said upper surface is distal to said support surface (paragraph 0056). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the specifics of the housing, as disclosed by Pugh, incorporated into Rosenberg in order to contain the simulated organs.

Referring to claim 7, Rosenberg, as modified by Pugh, teaches wherein the upper

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surface is no more than about 5 inches above the lower surface, the housing units 33 and 40 in Fig. 4 appear to have only a slightly bigger height than the mouse 44. Since a mouse is generally about 1.5 inches high, one could assume that housings 33 and 40 in Fig. 4 are probably about 2 or 3 inches high. Additionally, Pugh discloses that the size of the anatomical simulator and organs represent expected ranges of human size, shape, and other qualities (Paragraph [0038]). Therefore, if the invention were being used to simulate the anatomy of a baby or small child, the height of the anatomical simulator would be less than about 5 inches.

Referring to claim 8, Rosenberg, as modified by Pugh, teaches wherein said housing comprises at least one opening proximal to said upper surface thereof to access said pseudo skin (Figs. 14A-C, 15 & 16 of Pugh).

Referring to claim 9, Rosenberg, as modified by Pugh, teaches wherein said housing comprises a handle proximal to said anterior portion by which a user grips said apparatus during use (Fig. 8 shows two such appendages at the rightmost portion of the drawing of Pugh).

Referring to claim 10, Rosenberg, as modified by Pugh, discloses wherein: an insertion region for said end effector is defined at a site at which said end effector is received by said receiver (Fig. 1); said insertion region is proximal to a first region of said pseudo skin (Fig. 1); and a first end of said receiver is relatively closer to said insertion region and a second end of said receiver is relatively further from said insertion region (One end would be closer to a user then another end, depending on the location of the user with respect to the apparatus of Pugh).

Referring to claim 11, Rosenberg, as modified by Pugh, discloses wherein: said first skin-interaction technique comprises at least one of either palpation or occlusion (column 12 lines 46-49 of Rosenberg); and said first end of said receiver is closer to said anterior portion of said housing than said first device (Depending on the chosen location the first end could be closer to the anterior portion of the housing of Pugh). Referring to claims 12 & 18, Rosenberg, as modified by Pugh, discloses wherein: said first skin-interaction technique comprises at least one of either palpation or occlusion (column 12 lines 46-49 of Rosenberg); and an upper-most surface of said first device extends a greater distance above said lower surface of said housing than said first end of said receiver (Fig. 2 of Pugh).

Referring to claim 14, Rosenberg, as modified by Pugh, disclose wherein: said first skin-interaction technique comprises one of either palpation or occlusion (column 12 lines 46-49 of Rosenberg); and said second skin-interaction technique comprises skin-stretch (Figs. 14C, 15 & 16 of Pugh).

Referring to claim 15, Rosenberg, as modified by Pugh, teaches wherein at least some portion of said second device is closer to said anterior portion of said housing than said first device (paragraph 0012 of Pugh).

Referring to claim 16, Rosenberg, as modified by Pugh, teaches wherein at least some portion of said second device is closer to said anterior portion of said housing than said first end of said receiver (Items 16 & 20 in Fig. 1, paragraph 0037, items 26, 28, 29 & 30 in Fig. 3 & paragraphs 0041 & 0042 of Pugh).

Referring to claim 17, Rosenberg, as modified by Pugh, teaches wherein said first end

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of said receiver is closer to said anterior portion of said housing than said first device (Fig. 4).

Referring to claim 19, Rosenberg, as modified by Pugh, teaches wherein an upper-most surface of said first device extends further above said lower surface of said housing than an upper-most surface of said second device (Fig. 8 of Pugh).

Referring to claim 20, Rosenberg, as modified by Pugh, teaches wherein at least a portion of said receiver is disposed beneath an upper-most surface of said first device (Items 16 & 20 in Fig. 1, paragraph 0037, items 26, 28, 29 & 30 in Fig. 3 & paragraphs 0041 & 0042 of Pugh).

Referring to claim 21, Rosenberg, as modified by Pugh, teaches further comprising an electronics/communications interface, wherein: said electronics/communications interface receives signals from sensors that are associated with at least one of said first device or said receiver (paragraphs 0014-0017 of Pugh); and said electronics/communications interface is disposed beneath said pseudo skin and covered by said pseudo skin (wires located inside simulator of Pugh).

Referring to claim 22, Rosenberg, as modified by Pugh, teaches wherein said electronics/communications interface is closer to said posterior portion of said housing than said first device (depends on the location of the of the simulated organs or sensors with respect to the wires of Pugh).

Referring to claim 23, Rosenberg, as modified by Pugh, teaches wherein said electronics/communications interface is closer to said posterior portion of said housing than said receiver (depends on the location of the of the simulated organs or sensors

with respect to the wires of Pugh).

Referring to claim 24, Rosenberg, as modified by Pugh, teaches wherein said electronics/communications interface comprises a printed circuit board, and further wherein a major surface of said printed circuit board is disposed orthogonal to an uppermost surface of said first device (paragraph 0045 & Item 33 in Fig. 4 of Pugh). Referring to claim 26, Rosenberg discloses the apparatus of claim 25. Rosenberg does not disclose wherein the housing has a longitudinal axis, a first end of the longitudinal axis defines an anterior portion of the housing, a second end of the longitudinal axis defines a posterior portion of the housing, and in use, the anterior portion is proximal to a user and the posterior portion is distal to the user. However, Pugh teaches wherein the housing has a longitudinal axis, a first end of the longitudinal axis defines an anterior portion of the housing, a second end of the longitudinal axis defines a posterior portion of the housing, and in use, the anterior portion is proximal to a user and the posterior portion is distal to the user, Pugh discloses that the simulator may resemble a portion of a human body, which would include anterior and posterior regions, as defined by the regions spatial relationship with respect to a longitudinal axis (See Fig. 1 and 8). The proximity of a region with respect to a user would depend on the user's desired location when working with the invention. Therefore, a user could stand closer to the posterior region than the anterior, if the user went to that location. As a result, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include housing with a longitudinal axis, as disclosed by Pugh, incorporated into Rosenberg in order to determine the regions spatial relationships.

- 6. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg in view of Cunningham et al. (U.S. Publication Number 2003/0069719). Referring to claim 28, Rosenberg discloses the apparatus of claim 25 & wherein the mechanisms include a third mechanism (column 11 line 47 column 12 line 2) for simulating a second skin-interaction technique. Rosenberg does not disclose wherein the end effector is at least one of either a needle or a catheter. However, Cunningham et al. teaches wherein the end effector is at least one of either a needle or a catheter (Figs. 3 & 4). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a needle or catheter, as disclosed by Cunningham et al., incorporated into Rosenberg in order to be able to perform a simulation of the surface and subsurface anatomy of human skin.
- 7. Claims 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg/Cunningham et al. and further in view of Pugh.

Referring to claims 29-33 Rosenberg/Cunningham et al. discloses the apparatus of claim 28 and the second skin-interaction technique is at least on of either palpation or occlusion (column 12 lines 46-49. Rosenberg does not disclose said first skin-interaction technique is skin-stretch and at least a portion of the first mechanism is disposed at a substantially different position along the longitudinal axis than the second mechanism and third mechanism. However, Pugh teaches said first skin-interaction technique is skin-stretch (Figs. 14C, 15 & 16). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a skin-stretch

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technique, as disclosed by Pugh, incorporated into Rosenberg/Cunningham et al. in order to perform assessments.

With regard to the limitation wherein at least a portion of the first mechanism is disposed at a substantially different position along the longitudinal axis than the second mechanism and third mechanism (as in claim 29), and wherein the first mechanism is closer to the anterior portion of the housing than the second mechanism and third mechanism (as in claim 30), and wherein at least a portion of the second mechanism is disposed at a substantially different position along the longitudinal axis than the first mechanism and third mechanism (as in claim 31), and wherein the third mechanism is closer to the posterior portion of the housing than the first mechanism and second mechanism (as in claim 32), and wherein the portion of the second mechanism is flanked by the first mechanism and the third mechanism along the longitudinal axis (as in claim 33), Pugh discloses that a tactile sensor (i.e., second mechanism) may be placed at various locations with regard to simulated organs (i.e., first and third mechanisms), as previously described (Items 16 and 20 in Fig. 1; Paragraph [0037]; Items 26, 28, 29, and 30 in Fig. 3; Paragraph [0041-0042]). Therefore, a first organ could be located substantially differently along the longitudinal axis of the simulator, in relation to the locations of a sensor (i.e., second mechanism) and another organ (i.e., third mechanism), as recited in claim 29. Similarly, the locations of the sensor and organs could be located according to the arrangements recited in claims 30-33, as desired by a user.

Referring to claim 34, Rosenberg/Cunningham et al. discloses the apparatus of claim 28. Rosenberg/Cunningham et al. does not disclose wherein a user interacts with the first mechanism at a first site at an upper surface of the housing, and wherein the user interacts with the second mechanism at a second site at the upper surface of the housing, and wherein the user interacts with the third mechanism at a third site at the upper surface of the housing. However, Pugh teaches wherein a user interacts with the first mechanism at a first site at an upper surface of the housing, and wherein the user interacts with the second mechanism at a second site at the upper surface of the housing, and wherein the user interacts with the third mechanism at a third site at the upper surface of the housing. Pugh discloses that a user may interact with a plurality of simulated organs (i.e., mechanisms) via a plurality of openings on the simulator (Figs. 14A-C, 15, and 16). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include user interaction, as disclosed by Pugh, incorporated in to Rosenberg/Cunningham et al. in order to perform medical exams with direct manual contact with a body or organ surface.

8. Claims 36 & 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg.

Referring to claims 36 & 37, Rosenberg et al. discloses the apparatus of claim 35.

Rosenberg does not disclose expressly that the housing is no more than about 4 or 5 inches in height. Instead, Rosenberg indicates using a housing (column 5 lines 54-56).

At the time the invention was made, it would have been obvious matter of design choice to a person of ordinary skill in the art to have the housing having any measurements because Applicant has not disclosed that having adaptive architecture on a second computer provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Rosenberg's system, and applicant's invention, to perform equally well with the housing taught by Rosenberg or the claimed housing is no more than about 4 or 5 inches in height because both housings would perform the same function of contain the mechanism.

Therefore, it would have been prima facie obvious to modify Rosenberg to obtain the invention as specified in claims 36 & 37 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Rosenberg.

Response to Arguments

9. Applicant's arguments with respect to claims 1-40 have been considered but are moot in view of the new ground(s) of rejection.

Citation of Pertinent Prior Art

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Gregorio et al. (U.S. Publication Number 2003/0068607) teaches an interface apparatus with cable-driven force feedback and four grounded actuators.

Nicholls et al. (U.S. Patent Number 6,773,263) teaches a medical simulator.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kesha Frisby whose telephone number is 571-272-8774. The examiner can normally be reached on Mon. - Wed. 7-3pm & Thurs. - Fri. 7-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on 571-272-6696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert Pezzuto

Supervisor Patent Examiner

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